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14. ABSTRACT Background: It is estimated that there have been several hundred tibia fractures that have occurred in the global war on terror. Little is known about the long-term consequences of these injuries and their treatment. Objective: Our main objective is to determine significant predictors of poor outcome following open tibia fractures so that suitable modifications can be made to treatment and rehabilitative therapy. Of particular interest is an evaluation of differences in outcomes for various algorithms for the treatment of open tibia fractures. Specific Aims: We aim to: (1) describe the long-term consequences of open tibia fractures; (2) identify clinical and patient characteristics that explain variations in outcome; and (3) make recommendations for treatment adjustments. Study Design: Patients will be identified retrospectively. The retrospective cohort (numbering approximately 430) will consist of all soldiers who meet the inclusion criteria and were injured as of September 30, 2006 and cared for at one of the participating facilities. Principal sources of data will include: (1) clinical data abstracted from the medical record; (2) baseline interviews; and (3) a follow-up interview one-year following the baseline interview. Relevance: This long term follow-up will provide a unique opportunity to (1) examine the benefits of different treatment modalities for open tibia fractures in a military population; (2) identify ongoing needs for additional services; (3) provide the basis for targeted interventions; and (4) assist in assuring that these and future soldiers are provided with every opportunity for a good long-term outcome.				
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INTRODUCTION:

In 2006, the Johns Hopkins University Bloomberg School of Public Health received a grant from the Department of Defense to conduct a study to examine long-term orthopaedic outcomes in soldiers, sailors, airmen, and marines injured during the Global War on Terrorism (GWOT). The *Military Extremity Trauma and Amputation/Limb Salvage (METALS) Study* is a multi-center cohort study designed to establish procedures for a uniform, long term follow-up to better define the clinical, functional and quality of life outcomes following major orthopedic trauma. The study is a collaborative effort involving Walter Reed Army Medical Center (WRAMC), Brooke Army Medical Center (BAMC), National Naval Medical Center in Bethesda (NNMC), and the Naval Medical Center San Diego (NMCSD), and the Johns Hopkins University Bloomberg School of Public Health. The current study will enhance the METALS study by incorporating *all* open tibia fractures. It is estimated that there have been several hundred tibia fractures that have occurred in the global war on terror and many different techniques have been employed in treatment of these injuries, with varying degrees of success having been achieved. The objective of this study is to examine variations in the treatment of tibia fractures to include casting, functional bracing, uniplanar external fixation, multiplanar external fixation and intramedullary fixation. No single mode of treatment has been identified as being better than another. This study will help elucidate these treatment differences and document the long term outcomes following open tibia fractures.

BODY:

We have completed patient enrollment, all interviews and chart abstraction. The table below summarizes our progress and indicates the goals we have set for the coming year.

Critical Event	Completion Date
Study Infrastructure	
• Recruit and train medical record abstractor	Completed
Define Patient Population	
• Refine inclusion and exclusion criteria and develop protocol for identifying patients	Completed
Data Collection	
• Screen patient medical records for eligibility	Completed
• Revise interview and patient contact materials	Completed
• Develop contact database for survey research Firm (SSS)	Completed
• Send letters to potential participants	Completed
• Conduct patient interviews	Completed
• Abstract clinical data	Completed

Analysis of Data and Writing of Reports	
• Begin to develop analysis files	Completed
• Analysis	Month 24-29
• Preparation of manuscripts and final report	Month 29-30

We are in the process of amending the IRB approval to allow access to data from the Joint Theatre Trauma Registry (JTTR). Our request is two-fold. Our first request is for patient specific information on patients enrolled in the study who have provided us consent to access their medical record. Although we have already abstracted detailed information about their orthopaedic injuries, we are requesting supplementary data from the JTTR on ICD coded diagnoses, procedures, co-morbid conditions and AIS severity scores. The second request is for de-identified information on patients who were eligible but not enrolled in the study. This latter set of information is needed to ascertain potential bias in our results due to lower than expected enrollment rates. We have received approval from NNMC and the request is pending approval from the other 3 sites. Sponsor approval was received to extend the research project through 31 December 2010 with the final report due 31 January 2011.

KEY RESEARCH ACCOMPLISHMENTS:

- Identified and enrolled a total of 273 service men and women with open tibia fractures (125 (WRAMC); 79 (BAMC); 66 (NNMC) and 3(NMCSD). The enrolled service members are on average 30 years old and 37 months out from their injury at the time of the interview.
- Developed an analysis file linking the data from the chart abstraction with the Interview data.
- We are in the process of operationalizing variables for the analysis.

REPORTABLE OUTCOMES:

To date there are no reportable outcomes.

CONCLUSION:

Very little is known about the long term consequences of open tibia fractures and their treatment in a military setting. Of particular interest and concern is the status of service members once they are discharged from care at one of the participating facilities and either return home or return to active duty. The results of this study will have important implications for acute care treatment of these fractures. The study will also be used to identify ongoing (post-discharge) needs for additional services and provide the basis for targeting interventions and conducting focused research on carefully selected aspects of long-term recovery. Over the long term, the proposed research will assist in assuring that these service members are provided with every opportunity for a good long-term outcome.

REFERENCES:

None to date.

APPENDICES:

None.

SUPPORTING DATA:

None.